

**§ 520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.**

(a) *Specifications.* Each tablet contains amoxicillin trihydrate and clavulanate potassium, equivalent to either 50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid, or 100 milligrams of amoxicillin and 25 milligrams clavulanic acid, or 200 milligrams amoxicillin and 50 milligrams clavulanic acid or 300 milligrams amoxicillin and 75 milligrams clavulanic acid.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) *Staphylococcus aureus*, nonbeta-lactamase *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli*. Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

(iii) *Limitations.* Wounds, abscesses, cellulitis, and superficial/juvenile pyoderma: Treat for 5 to 7 days or for 48 hours after all signs have subsided. If no improvement is seen after 5 days of treatment, discontinue therapy and reevaluate diagnosis. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days. Not for use in dogs maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 62.5 milligrams (1 milliliter) (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing *S. aureus*, nonbeta-lactamase producing *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp. Also, treatment of urinary tract infec-

tions (cystitis) due to susceptible strains of *E. coli*.

(iii) *Limitations.* Skin and soft tissue infections: abscesses, cellulitis/dermatitis should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no response is seen after 3 days of treatment, therapy should be discontinued and diagnosis reevaluated. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998]

**§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.**

(a) *Specifications.* When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin with clavulanate potassium equivalent to 12.5 milligrams of clavulanic acid.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) producing *Staphylococcus aureus*, nonbeta-lactamase *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli*. Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

(iii) *Limitations.* Administer for 5 to 7 days or 48 hours after all symptoms subsided. Deep pyoderma may require 21 days, not to exceed 30 days. If no improvement is seen in 5 days, discontinue therapy and reevaluate the case. Not for use in dogs maintained for breeding. Federal law restricts this

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drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 62.5 milligrams (1 milliliter) (50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

(ii) *Indications for use*. Treatment of feline skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing *S. aureus*, nonbeta-lactamase *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, *Pasteurella multocida*, and *Pasteurella* spp.

(iii) *Limitations*. Administer 48 hours after all symptoms have subsided. If no improvement is seen after 3 days of treatment, discontinue therapy and re-evaluate diagnosis. Maximum duration of treatment should not exceed 30 days. Not for use in cats maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998]

### § 520.90 Ampicillin oral dosage forms.

#### § 520.90a Ampicillin capsules.

(a) *Specifications*. Each capsule contains 125 milligrams or 250 milligrams of ampicillin.

(b) *Sponsor*. See No. 000008 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 to 10 milligrams per pound of body weight, e.g., one 125 mg capsule per 14 to 25 pounds, given 2 to 4 times daily; for animals weighing 6 to 14 pounds, one capsule twice daily.

(ii) *Indications for use*. Treatment of urinary tract infections (cystitis) due to *Proteus* spp., hemolytic and non-hemolytic streptococci, beta hemolytic streptococci, and *Escherichia coli*. In upper respiratory tract infections tracheobronchitis (kennel cough), tonsillitis due to alpha and beta hemolytic streptococci, hemolytic positive staphylococci, *E. coli*, and *Proteus* spp. In infections associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations*. Bacteriologic studies to determine the causative organisms

and their susceptibility to ampicillin should be performed. Use of the drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins. Ampicillin is contraindicated in infections caused by penicillinase-producing organisms. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 125 milligrams twice daily; in more acute conditions three times daily.

(ii) *Indications for use*. Treatment of respiratory tract infections (bacterial pneumonia) due to alpha and beta hemolytic streptococci, hemolytic positive staphylococci, *E. coli*, and *Proteus* spp. In infections associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations*. Bacteriologic studies to determine the causative organisms and their susceptibility to ampicillin should be performed. Use of the drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins. Ampicillin is contraindicated in infections caused by penicillinase-producing organisms. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992]

#### § 520.90b Ampicillin trihydrate tablets.

(a) *Specifications*. Each tablet contains ampicillin trihydrate equivalent to 50 or 100 milligrams of ampicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 5 milligrams per pound of body weight, at 8-hour intervals, 1 to 2 hours prior to feeding, to be continued 36 to 48 hours after all symptoms have subsided. If no improvement is seen within 5 days, stop treatment, reevaluate diagnosis, and change therapy.

(2) *Indications for use*. Oral treatment of infections caused by susceptible organisms as follows: Upper respiratory infections, tonsillitis, and bronchitis due to *Streptococcus* spp., *Staphylococcus* spp., *Escherichia coli*, *Proteus mirabilis*,